

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 141-490 PCT	FOR FURTHER ACTION <small>see Form PCT/ISA/220 as well as, where applicable, item 5 below.</small>	
International application No. PCT/US06/09082	International filing date (<i>day/month/year</i>) 13 March 2006 (13.03.2006)	(Earliest) Priority Date (<i>day/month/year</i>) 30 March 2005 (30.03.2005)
Applicant ANDRX LABS, LLC		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 2 sheets.



It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the Report

a. With regard to the language, the international search was carried out on the basis of:



the international application in the language in which it was filed.



a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b))

b. ☐ With regard to any nucleotide and/or amino acid sequence disclosed in the international application, see Box No. I.

2. ☐ Certain claims were found unsearchable (See Box No. II)

3. ☐ Unity of invention is lacking (See Box No. III)

4. With regard to the title,



the text is approved as submitted by the applicant.



the text has been established by this Authority to read as follows:

5. With regard to the abstract,



the text is approved as submitted by the applicant.



the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regard to the drawings,

a. the figure of the drawings to be published with the abstract is Figure No. _____



as suggested by the applicant.



as selected by this Authority, because the applicant failed to suggest a figure.



as selected by this Authority, because this figure better characterizes the invention.

b. ☐ none of the figures is to be published with the abstract.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US06/09082

A. CLASSIFICATION OF SUBJECT MATTER

IPC: A61K 9/00(2006.01)

USPC: 424/400

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 424/400

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EAST

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 6,099,862 A (CHEN et al.) 08 August 2000 (08.08.2000), abstract, col. 2, lines 40-55, col. 3, lines 5-65 and cols. 5-7, examples 1-2.	1-46
Y	US 4,687,777 A (MEGURO et al.) 18 August 1987 (18.08.1987), col. 1, lines 5-15, col. 2, lines 15-65 and cols. 6-7, example 1.	1-46

☐ Further documents are listed in the continuation of Box C.

☐ See patent family annex.

* Special categories of cited documents:	
"A" document defining the general state of the art which is not considered to be of particular relevance	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"E" earlier application or patent published on or after the international filing date	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"O" document referring to an oral disclosure, use, exhibition or other means	"&" document member of the same patent family
"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

08 July 2006 (08.07.2006)

Date of mailing of the international search report

20 JUL 2006

Name and mailing address of the ISA/US

Mail Stop PCT, Attn: ISA/US
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Authorized officer

Michael Woodward

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PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:
MARTIN P. ENDRES
HELDMAN & COSTIGAN, P.C.
1185 AVENUE OF THE AMERICAS
NEW YORK, NY 10036

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Applicant's or agent's file reference 141-490 PCT		Date of mailing (day/month/year) 20 JUL 2006
FOR FURTHER ACTION See paragraph 2 below		
International application No. PCT/US06/09082	International filing date (day/month/year) 13 March 2006 (13.03.2006)	Priority date (day/month/year) 30 March 2005 (30.03.2005)
International Patent Classification (IPC) or both national classification and IPC IPC: A61K 9/00(2006.01) USPC: 424/400		
Applicant ANDRX LABS, LLC		

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201	Date of completion of this opinion 08 July 2006 (08.07.2006)	Authorized officer Michael Woodward Telephone No. (571) 272-1600
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Form PCT/ISA/237 (cover sheet) (April 2005)

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/US06/09082

Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of:

- ☒ the international application in the language in which it was filed
- ☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

- ☐ a sequence listing
- ☐ table(s) related to the sequence listing

b. format of material

- ☐ on paper
- ☐ in electronic form

c. time of filing/furnishing

- ☐ contained in the international application as filed.
- ☐ filed together with the international application in electronic form.
- ☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US06/09082

Box No. V Reasoned statement under Rule 43 bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims <u>1-46</u>	YES
	Claims <u>NONE</u>	NO
Inventive step (IS)	Claims <u>NONE</u>	YES
	Claims <u>1-46</u>	NO
Industrial applicability (IA)	Claims <u>1-46</u>	YES
	Claims <u>NONE</u>	NO

2. Citations and explanations:

Claims 1-46 lack an inventive step under PCT Article 33(3) as being obvious over Chen et al. (U.S. Patent No. 6,099,862) in view of Meguro et al. (U.S. Patent No. 4,687,777).

Chen et al. disclose a controlled release pharmaceutical dosage form comprising an active drug such as including antihyperglycemic drug such as biguanide, glipizide, pharmaceutically acceptable salt and the like, binders such as polyvinylpyrrolidone, absorption enhancer such as fatty acids, lubricant, excipients and the like (abstract, column 2, lines 40-55, column 3, lines 5-65, columns 5-6, examples 1-2). Chen et al. does not teach active drug such thiazolidinedione. However, Meguro et al. teaches this limitation.

Meguro et al. disclose active drug, thiazolidinedione and pharmaceutically acceptable salts thereof such as mineral salts (e.g. hydrochloride, hydrobromide, sulfate and the like) pharmaceutically acceptable carrier, excipients, such as lactose, starch, magnesium stearate, and their dosage form (column 1, lines 5-15, column 2, lines 15-45, and columns 6-7, example 1). Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to use the composition of Chen et al. since Meguro et al. disclose the similar composition for the same purpose. One of ordinary skill in the art at the time the invention was made would have been motivated to combine the composition of Chen et al. and Meguro et al. to make controlled release pharmaceutical dosage form of active drug in similar condition with the reasonable expectation of success.